Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

File: 2004/009839

Mrs Aleksandra Harasemcuk
40 Harcourt Avenue
Kealba VIC 3021

Dear Mrs Harasemcuk

Re: NSC-631570 (Ukrain) – Orphan Drug Application

I refer to your letter of 30 April 2004 seeking orphan drug designation for NSC-631570 (Ukrain), for the treatment of pancreatic cancer.

Consideration of your application **(Application No. 03-1456-4)** has been completed.

I have decided, pursuant to subregulation 16J(2) of the *Therapeutic Goods Regulations 1990* to designate NSC-631570 (Ukrain) as an orphan drug The indication is for the treatment of pancreatic cancer.

The Therapeutic Goods Administration (TGA) would appreciate advice on when you plan to submit an application to register the designated medicine. **It is strongly recommended that you meet with staff of the TGA prior to submitting such an application, to discuss data requirements**. If the indication in your application to register the medicine differs from that in your application for orphan drug designation, additional data may be required to demonstrate that orphan designation still applies.

Yours sincerely

Dr Leonie Hunt
Director
Drug Safety and Evaluation Branch
Delegate of the Secretary

Dated this 8th day of June 2004

FILE COPY

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of Orphan Products Development *(HF-35)*
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

August 20, 2003

Bohdan Hugel
US Agent for Now Pharm AG
3250 Glase Road
Danielsville, PA 18038

Re: Designation Request # 03-1693

Dear Mr. Hugel:

Reference is made to your request, submitted on behalf of Now Pharm AG, for orphan-drug designation dated February 27, 2003, of 5,5',5"-[phosphinothioylidyne-tris(imino-2,1-ethanediyl)] tris[5-methylchelidoninium] trihydroxide hexahydrochloride for the treatment of pancreatic cancer. Reference is also made to our acknowledgement letter dated April 8, 2003.

Pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bb), your request for orphan drug designation of 5,5',5"-[phosphinothioylidyne-tris(imino-2,1-ethanediyl)] tris[5-methylchelidoninium] trihydroxide hexahydrochloride for the treatment of pancreatic cancer is granted.

Please note that it is the active moiety of the drug and not its formulation that is designated. Please also note that if the above product receives marketing approval for an indication broader than what is designated, it may not be entitled to exclusive marketing rights under section 527 (21 U.S.C. § 360cc). Therefore, prior to final marketing approval, we request that you compare the product's designated orphan indication with the proposed marketing indication, and submit additional information to amend the orphan-drug designation if warranted.

Please submit to the Office of Orphan Products Development a brief progress report of drug development within 14 months after this date and annually thereafter until marketing approval (*see* 21 C.F.R. § 316.30). Finally, please notify this Office within 30 days of a marketing application submission for the product's designated use.

If you need further assistance in the clinical development of your product, please feel free to contact John J. McCormick, MD, at (301) 827-3666. Please refer to this letter as official notification and congratulations on obtaining your orphan-drug designation.

Sincerely yours,

Marlene E. Haffner, MD, MPH
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development